K001211

DEC - 4 2000

SECTION 11

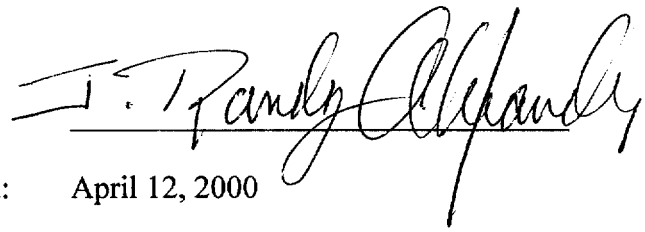
SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Submitter's name, address, telephone number, contact person, and date summary prepared;

a. Applicant: IntraLase Corporation
30 Hughes, Suite 206
Irvine, CA 92618

b. Contact Person: J. Randy Alexander
President and CEO



c. Date Summary Prepared: April 12, 2000

2. Name of device, including trade name and classification name:

a. Trade/Proprietary Name: IntraLase 600C Laser Keratome

b. Classification Name: Laser Keratome

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

Company:	IntraLase Corporation
Device:	IntraLase 600C Laser Keratome
Date Cleared:	December 17, 1999

Company:	KeraVision, Inc.
Device:	Intacs™ Vacuum System
Date Cleared:	April 28, 1999

4. **A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):**

The IntraLase 600C Laser Keratome is a precision ophthalmic surgical laser designed for use in performing lamellar corneal resections. The basic scientific concepts, significant physical and performance characteristics of the IntraLase 600C have been cleared for a different indication for use under K993153.

5. **Statement of intended use:**

The IntraLase 600C Laser Keratome is indicated for use in patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments. The new intended use is identical to that of the predicate device, the KeraVision Intacs Vacuum System.

6. **Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.**

The technological characteristics of the IntraLase 600C Laser Keratome have already been cleared under K993153 for a slightly different intended use that is, however, related to these technological characteristics. Specifically, the IntraLase 600C Laser Keratome creates lamellar corneal resections through precise microphotodisruptions of tissue created by tightly focused ultrashort pulses, in lieu of mechanical resection or cutting as by using the KeraVision Intacs Vacuum System. The differences in the laser keratome represented by the proposed additional indication of tunnel creation for placement of corneal ring segments are limited to the laser scanning pattern and the related software controls. The design, materials and characteristics of the laser keratome are the same irrespective of the indication for use.

7. **Brief summary of nonclinical tests and results:**

The IntraLase 600C Laser Keratome has been designed and will be tested to applicable safety standards. In addition, the IntraLase 600C was found to perform equivalently to the predicate device, the KeraVision Intacs Vacuum System, with respect to the creation of corneal tunnels in extensive *ex vivo* and *in vivo* studies. Thus, the technological differences between the IntraLase 600C Laser Keratome and the KeraVision Intacs Vacuum System do not raise any new issues of safety, effectiveness or performance of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2000

Mr. J. Randy Alexander
President and Chief Executive Officer
IntraLase Corporation
30 Hughes, Suite 206
Irvine, California 92618

Re: K001211
Trade Name: IntraLase 600C Laser Keratome
Regulatory Class: II
Product Code: GEX, HNO
Dated: November 27, 2000
Received: November 28, 2000

Dear Mr. Alexander:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001211

Device Name: IntraLase 600C Laser Keratome

Indications for Use:

The IntraLase 600C Laser Keratome is an ophthalmic surgical laser indicated for use in patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K001211

Perscription Use ✓ OR Over-The-Counter Use ____

(Optional Format 1-2-96)